Rapid antigen diagnostic testing for the diagnosis of group A beta-haemolytic streptococci pharyngitis

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ABSTRACT

Background. It is difficult to make a diagnosis of group A beta-haemolytic streptococci (GABHS) pharyngitis solely on clinical findings. The McIssac scoring system has been recommended as a reliable clinical tool for diagnosis. The rapid antigen detection test (RADT) has been shown to considerably increase the number of patients who are appropriately treated for streptococcal pharyngitis, compared with the use of traditional throat cultures. It also reduces the time to start treatment. We evaluated the diagnostic utility of RADT in comparison with throat swab culture.

Methods. Using the McIssac scoring system, RADT and throat swab cultures in those with a McIssac score of 3 or more, we evaluated 165 children (aged 2–15 years) with a clinical diagnosis of pharyngitis.

Results. GABHS pharyngitis was confirmed in 41 (24.8%) by throat swab culture and RADT was positive in 39(23.6%). Only in 2 (4.9%) children, RADT was negative but throat swab was positive. The sensitivity of RADT was 89.7% and specificity was 98.4% with a positive predictive value of 94.6%, negative predictive value of 96.9% and diagnostic accuracy of 96.4%.

Conclusion. RADT performed was observed to have high sensitivity and sensitivity for the diagnosis of GABHS pharyngitis in contrast to an earlier report from India. Our observations suggest that using RADT as a point-of-care test is reliable and cost-effective and needs to be propagated in Indian settings where facilities for throat swab culture are not routinely available and also because clinical diagnosis based on scoring systems are comparatively less reliable.

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INTRODUCTION

It is difficult to make a diagnosis of group A beta-haemolytic streptococci (GABHS) pharyngitis solely on clinical findings. The McIssac scoring system has been recommended as a reliable clinical tool for diagnosis.[1] Rapid antigen detection test (RADT) has been shown to considerably increase the number of patients who are appropriately treated for streptococcal pharyngitis, compared with the use of traditional throat cultures,[1] and also to reduce the time to start treatment. We evaluated the diagnostic utility of RADT in an Indian setting and determined its sensitivity and specificity in comparison with the gold standard throat swab culture for GABHS.

METHODS

This prospective study included children (aged 2–15 years) with sore throat presenting to the outpatient department (September 2013 to August 2014) of Kanchi Kamakoti CHILDS Trust hospital. We evaluated consecutive children who had not received any antibiotic for their present illness and within the past 30 days. The McIssac score was assessed in all of them: 1 point for each of the following criteria: history of temperature >38 °C (100.4 °F); absence of cough; tender anterior cervical adenopathy; tonsillar swelling or exudates; rhinorrhoea; palatal petechiae; and skin rash. Only those with the McIssac score of 3 or more were included. Demographic and clinical details were collected. Those clinically diagnosed to have viral illnesses such as herpangina, herpes simplex or Epstein–Barr virus (EBV) infections and those children whose parents did not give consent were excluded. Herpangina was diagnosed in the presence of an acute febrile illness associated with small vesicular or ulcerative lesions on the posterior oropharyngeal structures (enanthem). Herpes simplex infection was diagnosed if typical lesions of gingivostomatitis were present. Clinical diagnosis of EBV infection was made if exudative tonsillitis was present with generalized or cervical lymphadenopathy and splenomegaly. Among the 684 children screened, 519 were excluded as they were diagnosed clinically as having a viral infection. All the 165 children included in the study underwent two throat swabs—one for RADT (Rapid VIDI Test Strep A, Czech Republic) and another for culture using blood agar plate. The microbiology laboratory was blinded to the results of RADT. Sensitivity, specificity, positive predictive value and negative predictive value of RADT were assessed using culture as the gold standard using the Wilson scoring system.

RESULTS

Forty-one of 165 children (24.8%) were confirmed to have GABHS pharyngitis by throat swab culture. Fever >38 °C was the most common clinical feature in confirmed cases followed by anterior cervical adenopathy and exudates in the tonsils. The other features observed were palatal petechiae, cough, rhinorrhoea, abdominal pain and rash (Table I). Scarlet fever and Kawasaki disease were confirmed in 2 children with a positive culture. There were 74 (44.8%) 2–5-year-old children and 14 were positive (8.5%).

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TABLE I. Clinical parameters observed in our study

Parameter	*n* (%)
Sore throat	41 (100)
Temperature >101 °F	33 (80.5)
Cough	8 (19.5)
Rhinorrhoea	2 (4.9)
Palatal petechiae	3 (7.3)
Vomiting/pain abdomen	5 (12.2)
Anterior cervical adenopathy	23 (56.1)
Skin rash	5 (12.2)

Sixty-eight children (41.2%) were 5–10 years of age and 17 were positive (10.3%). Twenty-three children were 10–15 years old and 8 (4.8%) were positive.

RADT was positive in 39 of 165 (23.6%) children and culture was positive in 41 (24.8%) children. Only in 2 (4.9%) children RADT was negative but throat swab was positive. Overall, the sensitivity of RADT was 89.7% with a confidence interval (CI) of 76.4–95.9, and specificity was 98.4% (CI 94.4–99.6). The positive predictive value was 94.6% (CI 82.3–98.5) and the negative predictive value was 96.9% (92.2–98.8). The diagnostic accuracy was 96.4% (CI 92.3–98.3).

DISCUSSION

Physicians relying solely on clinical judgement for diagnosis of GABHS pharyngitis often overestimate the likelihood of a streptococcal aetiology. Many clinical scoring systems have been used to identify patients who are likely to have GABHS pharyngitis. The most frequently used scoring system, the McIssac score has been associated with a positive laboratory test for GABHS in <70% of children with pharyngitis when the scores were >4.

The guidelines of the Infectious Diseases Society of America (IDSA) suggest that swabbing the throat and testing for GABHS pharyngitis by RADT and/or culture should be done because the clinical features alone do not reliably discriminate between GABHS and viral pharyngitis except when overt viral features such as rhinorrhoea, cough, oral ulcers and/or hoarseness are present and that positive RADTs do not necessitate a back-up culture because they are highly specific. Specificities of these tests are generally high, but the reported sensitivities vary considerably as with throat swab cultures, sensitivity of these tests is highly dependent on the quality of the throat swab specimen, the experience of the person doing the test, and the rigor of the culture method used for comparison.

In a recent study, five RADT kits were reported to have a specificity of 100%.[2] In earlier reports, the specificity of RADT has been ≥95% but the sensitivity has varied between 70% and 90%.[3–11] Reports on the utility of RADT have been sparse in the Indian context in spite of the high incidence of rheumatic fever. In the only study on RADT published from India, a low sensitivity of 55.5% and specificity of 100% was reported. But the same kit had been earlier reported to have a sensitivity of 95.9%.[12] The high specificity and sensitivity observed in our study reinforces the need to apply IDSA guidelines on RADT for treatment of GABHS pharyngitis in Indian settings.

When cost is considered in the management of pharyngitis, RADTs have been shown to be the more cost-effective when compared directly with culture,[13] and this is in addition to the advantage of considerably reduced time for accurate diagnosis. Considering the low cost of the test (approximately ₹200), the benefits are many, particularly in terms of antibiotic stewardship and avoidance of unnecessary antibiotic therapy for upper respiratory symptoms of pharyngitis, which are mostly viral in origin. In our study, RADT had much higher values of sensitivity and specificity than reported in earlier studies using the McIssac score, the most widely used clinical assessment tool. Other factors that may have an impact on the sensitivity and specificity of the RADTs, such as the type of throat swab and sampling techniques, also need to be investigated in well-designed studies, to improve the diagnostic accuracy of RADTs.

The high yield in our series might be due to the clinical assessment and throat swab testing being performed by trained medical personnel, which followed a specific protocol after in-house training. Throat swabs were obtained by only two of the authors and clinical details were also captured by them—this could have resulted in a high yield for RADT. However, the American Academy of Pediatrics and IDSA recommend confirmation of negative RADT results by a throat culture because the sensitivity of RADTs is estimated to be insufficient, at about 85%.[5] In our series, only in 2 (4.9%) children the RADT was negative but the culture was positive. RADT sensitivity has been reported to be influenced by the physician performing the test (range 56%–96%, p=0.01) and higher for physicians with hospital-based clinical activity in addition to office-based practice.[14]

The limitations of our study include non-performance of follow-up cultures to exclude carrier states and a tertiary care hospital-based setting. A similar high sensitivity and specificity might be difficult to achieve in primary care settings.

We conclude that RADT has a high sensitivity and specificity for diagnosis of GABHS pharyngitis in Indian settings. Throat swab culture, which is considered the gold standard for diagnosis, is difficult to do routinely in community settings because of lack of laboratory facilities. We recommend using RADT as a point-of-care test in the diagnosis of GABHS pharyngitis in India, which will improve antibiotic stewardship in paediatrics.

Conflicts of interest. None

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